

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF  
PENNSYLVANIA

RAE SCHIFF,	: Civil Action: 2:12-cv-00264 AJS
	:
Plaintiff,	:
vs.	:
	:
DENNIS J. HURWITZ, M.D., HURWITZ	:
CENTER FOR PLASTIC SURGERY, P.C.;	:
INVASIX, Ltd.; ESSEX INSTITUTIONAL	:
REVIEW BOARD, INC.; and an UNKNOWN	:
ENTITY, agent for INVASIX, Ltd.,	:
	:
Defendants.	

**PLAINTIFF’S SUPPLEMENTAL MOTION  
FOR SPECIAL ORDER OF SERVICE OF PROCESS**

Plaintiff, RAE SCHIFF, through her attorneys GOLDBERG, PERSKY and WHITE, PC, and HOWARD M. LOUIK, Esq. pursuant to RULE 4(f)(3) of the FEDERAL RULE OF CIVIL PROCEDURE petitions for the Court to determine and order alternate means to effect service of process over defendant, Invasix, Ltd. ***and to have said defendant designate its domestic agent*** and in support thereof sets forth as follows:

1. On April 23, 2012 defendant, Invasix, Ltd. (“Invasix”) filed a motion to dismiss under Fed.R.C.P. 12(b)(5) alleging plaintiff had failed to effectuate proper service of process over defendant. (Doc. 24)
2. This litigation arises out of the use of a medical device in an investigational setting. The device (“Invasix Device”) was manufactured by defendant Invasix, an Israeli corporation.

3. The complaint alleges that to circumvent federal oversight through the Food and Drug Administration, Invasix designated its device as a non significant risk (NSR) device and received approval from defendant, Essex Institutional Review Board, to begin investigational trials of the Invasix Device. (Complaint, ¶s 33, 44, 59, 155).
4. Had the Invasix Device been properly classified as either a Class III or Class II “significant risk” (SR) device, Invasix would have been required to secure either FDA premarket approval or an Investigational Device Exemption (IDE) approval order. (Complaint, ¶s 24, 28).
5. Under the regulatory scheme adopted by the FDA, a foreign company such as Invasix, cannot sponsor an investigational trial, but must have an agent located in the United States act as a sponsor. 21 C.F.R. § 812.18(a)
6. The identity of Invasix’s domestic agent is presently unknown although plaintiff’s counsel requested that the identity of the agent be disclosed at the time of the Rule 26(f) conference.
7. From information received from Invasix’s counsel it appears that Invasix was acting as the sponsor the Invasix Device clinical trial without a domestic agent as required by law.
8. Invasix should not be permitted to export a device to the United States, impede service of process in a suit based on that device by violating federal regulations, and benefit from that violation by successfully challenging the form of service that Plaintiff has chosen. Plaintiff has been placed at a severe disadvantage by having to seek international means of service when a domestic agent should be amenable to service through the usual domestic channels.

9. Invasix also maintains a web site at <http://bodytite.ca/about-invasix> in which it identifies that it has at least two corporate headquarters; a “North America” office located in Ontario, Canada and an “International” office located in Yokneam, Israel. None of the other offices identified on the website in Germany, the United States, Hong Kong or Tokyo are identified as Invasix’s corporate headquarters.
10. In its motion to dismiss Invasix alleges that its Canadian headquarters is actually occupied by a subsidiary corporation despite the public statements on its website.
11. On April 23, 2012 plaintiff filed an affidavit of service attaching as an exhibit the mailing and tracking information sheet showing that Invasix had been properly served with service of process on in Canada March 14, 2012.
12. Plaintiff believes that she has appropriately served Invasix in Canada even if the Ontario headquarters is occupied by a subsidiary corporation. *Trump Taj Mahal Associates v. Hotel Services, Inc.*, 183 F.R.D. 173, 178-79(D.N.J. 1998); *Schlunk v. Volkswagenwerk Aktiengesellschaft*, 503 N.E.2d 1045, 1048-49.
13. On May 18, 2012 this Court rejected Invasix’s allegations that service had not been properly made over the defendant in Canada. See Doc. 43. On the same date it also denied as moot, by text entry only, Plaintiff’s Motion for Special Order for Special Service of Process.
14. While this Court has denied Invasix’s motion under Fed.R.C.P. 12(b)(5) that service of process was not proper over defendant, plaintiff nonetheless, requests that Invasix (a) identify on the record its domestic agent so that service of process can be made on the agent which is currently identified in the caption as “Unknown Entity” and (b) the Court provide a method of alternative service under RULE 4(f)(3) by:

- a) Requiring Invasix's counsel to disclose within five (5) days the identity of Invasix's domestic agent for the purpose of the Invasix Device investigational trial, including said party's mailing address, office manager, office managers email address and fax number.
  - b) Requiring Invasix's counsel to disclose within five (5) days whether Invasix has received service of process in Israel including the Summons, Complaint, Notice of Alternative Dispute Resolution and Form USM-94.
  - c) Requiring counsel who has entered an appearance on behalf of Invasix to accept service on its behalf by accepting the summons and complaint via certified mail, return receipt requested.
  - d) Authorizing alternate service of process over Invasix, Ltd. in accordance with the terms of the attached proposed order.
15. The means of alternate service under RULE 4(f)(3) is limited only to the extent that alternate service is directed by the court, is not prohibited by an applicable international agreement and it comports with constitutional notions of due process. See *Rio Properties, Inc. v. Rio International Interlink*, 284 F.3d 1007 (9<sup>th</sup> Cir. 2002).
16. Alternate service of process is often employed where a foreign defendant seeks to evade service of process. See *International Controls Corp. v. Vesco*, 593 F.2d 166 (2<sup>nd</sup> Cir. 1979) (where defendant located overseas has demonstrated ability to evade service of process, actual delivery of the summons and complaint to defendant is not required).
17. A party need not demonstrate the defendant's evasion of service of process to proceed to a request for alternate service. See *RSM Production Corp. v. Friedman*, 2007 U.S. Dist.LEXIS 58194 (S.D. NY 2007) (request for alternate service of process pursuant

to Rule 4(f)(3) does not require any demonstration of evasion by defendant located abroad in order to secure substituted service).

WHEREFORE, for all the foregoing reasons, plaintiff, Rae Schiff, respectfully requests the Court, pursuant to RULE 4(f)(3) to direct service of process by alternate means be effected against Invasix, Ltd. and to have said defendant designate its domestic agent which method comports with due process and is reasonably calculated to provide defendant with notice and an opportunity to defend.

Respectfully submitted,

By: **/s/ Howard M. Louik**  
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